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EXAMINER

MILLER, MARINA I

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1631

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Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Applicants' election traverse of Group I (claims 1-8, 21-22, and 29-34) in the reply filed 10/21/2005 is acknowledged.

The traversal is on the ground(s) that the subject matter of the instant claims is sufficiently related and a search and examination of the entire application would not place a serious burden on the examiner. Applicants amended claims of Groups II and IV to depend from claim 1 of elected Group I. In light of the amendment, claims 9-19, 21-22, and 23-36 are considered elected.

Applicants further elected without traverse the following species:

Species A: total distance traveled over a different period of time.

Species B: speed.

Species C: flies not contacted with a test agent.

Claims 1-6, 9-12, 15-17, 21-26, and 29-35 are pending.

Claims 7-8, 13-14, 18-20, 27-28, and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claims.

An action on the merits of claims 1-6, 9-12, 15-17, 21-26, and 29-35, as they read on the elected species, follows.

Information Disclosure Statement

Information Disclosure Statements (IDS) filed 9/14/2004 and 8/17/2004 have been considered in full.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-12, 15-17, 21-26, and 29-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claims 9, 10, 15, and 23, as amended, depend from claim 1 and comprise additional steps of, for example, determining a trait, ranking agents, determining phenoprofiles, comparing phenoprofiles, selecting agents, and determining whether agents modify, delay, or prevent onset of a trait. However, a method comprising steps of claim 1 AND further comprising steps of determining a trait, ranking agents, determining phenoprofiles, comparing phenoprofiles, selecting agents, and determining whether agents modify, delay, or prevent onset of a trait do not have support in the specification, claims, or drawings, as originally filed. The specification only supports a method of claim 1 OR the methods recited the steps of claims 10, 15, and 23 as they were originally presented. Applicants do not point to support in the originally filed disclosure for the claim amendments, and none is apparent, as set forth above. For these reasons, the claims are rejected for reciting new matter.

Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9-12, 15-17, 21-26, and 29-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 recite in the preamble “screening for the effect of a test agent on a population.” It is not clear whether the method screens for an agent (for example, an agent which affects a known train (*e.g.*, speed)) or the effect of an agent (for example, how profoundly different agents affect a selected train (*e.g.*, an agent which lowers speed of a fly more dramatically compare to other agents), *etc.* As the intended limitation is not clear, claims 1-6, 9-12, 15-17, 21-26, and 29-35 are indefinite.

Claims 1 and 2 recite in the preamble “screening for the effect of a test agent on a population.” The method further recites steps of providing a population, administering a test agent, creating an image of a trait, and correlating the traits with the effect of the test agents. The method does not recite a step of screening (selecting) an effect and/or agent. Thus, the relationship between the preamble and the steps is not clear because it is not clear whether the step of “correlating” is intended to result in “screening” (*i.e.*, selecting) an effect and/or agent. As the intended limitation is not clear, claims 1-6, 9-12, 15-17, 21-26, and 29-35 are indefinite.

Claims 1 and 2 recite in the preamble “screening for the effect of a test agent on a population.” There is insufficient antecedent basis for this limitation in the claim. Claim 1 does

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not recite “an effect” of an agent. As the intended limitation is not clear, claims 1-6, 9-12, 15-17, 21-26, and 29-35 are indefinite.

Claims 1 and 2 recite steps of providing a population, administering a test agent, creating an image of a trait, and correlating the traits with the effect of the test agents. The relationship between the method steps is not clear. Specifically, the step of administering an agent does not seem to relate to a step of creating an image showing a trait because it is not clear whether the image is created for the population after and/or before administering the agent. Further, the step of correlating the traits of the population does not seem to relate to other steps because “the trait of the population” and “the effect of the test agent” are not determined in other method steps. As the intended limitation is not clear, claims 1-6, 9-12, 15-17, 21-26, and 29-35 are indefinite.

Claims 1 and 2 recite the limitation “the traits of the population.” There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite “traits of the population” and only recites a “trait of specimens in the population.” As the intended limitation is not clear, claims 1-6, 9-12, 15-17, 21-26, and 29-35 are indefinite.

Claims 1 and 2 recite the limitation “the traits of the population.” It is not clear whether the limitation “traits of the population” is intended to mean different traits pertaining to different groups of the population, different traits pertaining to different specimens of the population, or a set of average/normalized traits for the entire population obtained by averaging/normalizing traits of specimens in the population. As the intended limitation is not clear, claims 1-6, 9-12, 15-17, 21-26, and 29-35 are indefinite.

Claims 1 and 2 recite the limitation “correlating the traits of the population with the effect of the agents administered to the population.” The metes and bounds of the step comparing the

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traits with the effect is not clear because criteria, algorithm, and/or specific directions of performing the comparison is not clear, and neither the claims nor the specification defines the limitation. As the intended limitation is not clear, claims 1-6, 9-12, 15-17, 21-26, and 29-35 are indefinite.

Claims 1 and 2 recite the limitation “correlating the traits of the population with the effect of the agents administered to the population.” It is not clear what is correlated in this step, *e.g.*, different traits of the population which was administered (affected) with an agent or traits of the population after administration of an agent and the effect of the agent on the traits. As the intended limitation is not clear, claims 1-6, 9-12, 15-17, 21-26, and 29-35 are indefinite.

Claims 3-4 recite a step of determining a trait. It is not clear where the step of determining fits into claims 1 or 2 from which claims 3-4 depend, *e.g.*, before/after creating an image, after correlating, *etc.* It is further unclear whether “determining” is intended to mean “selecting,” “identifying,” or “altering” a trait or some other step. As the intended limitation is not clear, claims 1-6, 9-12, 15-17, 21-26, and 29-35 are indefinite.

Claims 6 and 21 recite the limitation “wherein said step of determining comprises.” It is not clear what limitation is intended because none of the parental claims recites a step of determining. As the intended limitation is not clear, claims 6 and 21 are indefinite.

Claims 9, 10, 15, and 23 recites steps of determining, ranking, comparing phenoprofiles, and selecting an agent. It is not clear what limitation is intended because it is not clear whether the steps recited in claims 9, 10, 15, and 23 are intended to substitute the steps of claim 1, and if not, then it is not clear where the steps fit within claim 1. As the intended limitation is not clear, claims 9-12, 15-17, 21-26, and 29-35 are indefinite.

Claims 9 and 10 recite the limitation “method of claim 1, wherein a plurality of populations is contacted” with an agent. It is not clear what limitation is intended because claim 1 is directed to a method for screening an effect on a population. It is noted that if claims 9-10 are intended to screen for an effect of an agent on a plurality of populations, then claims 9-10 might not be enabling. As the intended limitation is not clear, claims 9-12, 21-22, and 29-35 are indefinite.

Claim 9 recites the limitation “to produce.” It is not clear whether “producing” is intended to be an active, positive step of the method. As the intended limitation is not clear, claims 9, 12, 21-22, and 29-35 are indefinite.

Claims 9 and 23 recite the limitations “a reference phenoprofile” and “an agent phenoprofile.” It is not clear what limitation is intended and neither the claims nor the specification specifically defines the limitations. As the intended limitation is not clear, claims 9, 12, 21-23, 25-26, and 29-35 are indefinite.

Claim 9 recites though limitation “a reference phenoprofile defined by ... trait as measured in a reference population.” It is not clear what is “measured,” a reference phenoprofile or a trait. As the intended limitation is not clear, claims 9, 12, 21-22, and 29-35 are indefinite.

Claims 10 and 15 recite the limitation “selecting an agent ... based on the comparison.” The metes and bound of the claims is not clear because the parameters and/or criteria of “selecting ... base on the comparison” is not clear and neither the claims nor the specification defines the limitation. As the intended limitation is not clear, claims 10-12, 16-17, 24-26, and 29-35 are indefinite.

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Claim 23 recites the limitations “a trait” in line 14 and “a test agent” in line 15. Claim 23, as amended, depends from claim 1. It is not clear whether “a trait” and “an agent” of claim 23 is intended to be a different trait and agent from the trait and the agent recited in line 13 of claim 23 and in claim 1. As the intended limitation is not clear, claims 23, 25-26, 29-30, and 35 are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 9-12, 15-17, 21-22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bainton, *Curr. Biol.*, 10:187-194 (2000).

Bainton discloses a method for screening an effect of a test compound (e.g., cocaine, ethanol) on a population of *Drosophila* flies (p. 187). The method comprises steps of providing a population of flies, administering test compounds, creating a digital image of a trait (p. 193, Materials and Methods; fig. 3), and correlating the trait of the population with the effect of the agent (p. 187, right col. through p. 188, left col.). Thus, Bainton anticipates claim 1. Bainton

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discloses a plurality of populations (*e.g.*, wild-type flies, wild-type flies fed on 3IY, wild-type flies fed on 3IY and cocaine, wild-type flies fed on 3IY and nicotine, *etc.*). Bainton further discloses monitoring multiple traits (*e.g.*, locomotion, paths, velocity, degree of turning, climbing, p. 187-189; 193). Thus, Bainton anticipates claim 2. Bainton discloses determining multiple traits (p. 187-189; 193), thereby anticipating claims 3-4 and 6. Bainton discloses total distance traveled over a period of time (p. 188, left col. discloses climbing of flies over a one-foot-long cylinder), thereby anticipating claim 5. Bainton discloses determining traits for each population to produce an agent phenoprofile (*e.g.*, fig. 2 presents phenoprofiles of different populations contacted with different agents). Bainton discloses “ranking” of compounds (*e.g.*, flies treated with 3IY show a significant but different reduction in their sensitivity to the effect of cocaine and nicotine, p. 188-189, fig. 2). Thus, Bainton anticipates claim 9. Bainton discloses treating flies with 3IY agent before flies are exposed to cocaine, nicotine, and ethanol (p. 189). Bainton discloses that the treated population withstands a higher dose of cocaine (200mcg v. 100 mcg in untreated population). Bainton further discloses synergistic effect caused by simultaneous administration of cocaine and nicotine and that the effect is greatly diminished in flies pre-treated with 3IY (p. 192). Also Bainton discloses that the sedative effect of ethanol is not altered by 3IY (p. 192). Thus, Bainton discloses “selecting” an agent (3IY, cocaine, nicotine, and ethanol) with desired biological activity based on comparison of an agent and a reference phenoprofiles (fig. 1-2, 4-5 and p. 189, 191-192), thereby anticipating claims 10-12, 15-17, 21-22. Bainton discloses a population of insects used to characterize mammalian diseases (drug abuse involving dopaminergic system, p. 193).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 9-12, 15-17, 21-26, 29-31, and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunner, US 2003/0028327, in view of Hendricks, *Neuron*, 25:129-138 (2000).

Brunner discloses a method of monitoring behavior information in animals and screening for the effect of agents (abstract). Brunner discloses steps of providing a population of animals, administering an agent, creating an image of traits, and comparing the traits with the effect of an agent ([0031]-[0037], [0043], [0046]-[0051], and Example 1, p. 14-15). Brunner discloses creating images for multiple traits, [0051], [0111], [0229]-[0231]. Brunner discloses multiple populations of animals (*e.g.*, test and control) [0238]. Brunner discloses determining behavior (trait) of populations ([0149]-[0174]). Brunner discloses traits “total distance traveled over a period of time” and “speed” (horizontal and vertical movement (locomotion activity), fig. 11-13 and Example 1, p. 14). Brunner discloses producing and comparing phenoprofiles ([0113]-[114], [0173], [0246], Example 1 at p. 14, and fig. 11-13). Brunner discloses “ranking” agents ([0051], [0174], [0246]). Brunner discloses selecting agents based on comparison of test and reference phenoprofiles ([0051], fig. 13).

Brunner does not specifically disclose an insect population.

Hendricks discloses using *Drosophila* model for studying a sleep state comprising administering drugs to a transgenic flies and observing behavior of individual flies and groups (*e.g.*, locomotion) by creating an image (videotaping) (p. 129-130, 136, fig. 1). Hendricks also discloses genetic mutants resulting in a loss of function (*e.g.*, lack of a rest rebound, p. 135, right col.). Hendricks discloses sleep-related changes in central neural function and involvement of the adenosine receptor in sleep alteration (p. 129). Hendricks discloses transgenic flies (p. 130, section *Animals*).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Brunner to monitor behavior of insects, such as taught by Hendricks, where the motivation would have been to facilitate the genetic study of multiple mammalian diseases on a *Drosophila* model, as taught by Hendricks, p. 129 and 136.

Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunner, US 2003/0028327, in view of Hendricks, *Neuron*, 25:129-138 (2000), as applied to claims 1-6, 9-12, 15-17, 21-26, 29-31, and 34-35, above, and in view of Chan, *Cell Death and Differentiation*, 7:1075-1080 (2000).

Brunner and Hendricks make obvious the method of claims 1-6, 9-12, 15-17, 21-26, 29-31, and 34-35, as set forth above.

Brunner and Hendricks do not disclose a gene encoding a polypeptide with an expanded polyglutamine.

Chan discloses using transgenic *Drosophila* flies for elucidating mechanisms of human neurodegenerative diseases (abstract). Chan discloses *Drosophila* models for human polyglutamine disease and a polyglutamine peptide (p. 1078).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Brunner and Hendricks to use *Drosophila* models for a human polyglutamine disease wherein a transgenic fly carries a gene encoding a polyglutamine polypeptide, such as taught by Chan, where the motivation would have been to facilitate the genetic study of multiple mammalian diseases on a *Drosophila* model, as taught by Chan, p. 1075.

Claims 23, 25-26, 29-31, and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bainton, *Curr. Biol.*, 10:187-194 (2000), as applied to claims 1-6, 9-12, 15-17, 21-22, and 24 above, in view of Hendricks, *Neuron*, 25:129-138 (2000).

Bainton teaches the method of claims 1-6, 9-12, 15-17, 21-22, and 24, as set forth above. Bainton does not specifically teach transgenic insects.

Hendricks discloses using *Drosophila* model for studying a sleep state comprising administering drugs to a transgenic flies and observing behavior of individual flies and groups (*e.g.*, locomotion) by creating an image (videotaping) (p. 129-130, 136, fig. 1). Hendricks also discloses genetic mutants resulting in a loss of function (*e.g.*, lack of a rest rebound, p. 135, right col.). Hendricks discloses sleep-related changes in central neural function and involvement of the adenosine receptor in sleep alteration (p. 129).

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It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Bainton to monitor behavior of transgenic insects, such as taught by Hendricks, where the motivation would have been to facilitate the genetic study of multiple mammalian diseases on a *Drosophila* model, as taught by Hendricks, p. 129 and 136.

Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bainton, *Curr. Biol.*, 10:187-194 (2000), in view of Hendricks, *Neuron*, 25:129-138 (2000), as applied to claims 1-6, 9-12, 15-17, 21-26, 29-31, and 34-35, and in view of Chan, *Cell Death and Differentiation*, 7:1075-1080 (2000).

Bainton and Hendricks make obvious claims 1-6, 9-12, 15-17, 21-26, 29-31, and 34-35, as set forth above.

Bainton and Hendricks do not disclose a gene encoding a polypeptide with an expanded polyglutamine.

Chan discloses using transgenic *Drosophila* flies for elucidating mechanisms of human neurodegenerative diseases (abstract). Chan discloses *Drosophila* models for human polyglutamine disease and a polyglutamine peptide (p. 1078).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Bainton and Hendricks to use *Drosophila* models for a human polyglutamine disease wherein a transgenic fly carries a gene encoding a polyglutamine polypeptide, such as taught by Chan, where the motivation would have been to facilitate the genetic study of multiple mammalian diseases in a widely used *Drosophila* model, as taught by Chan, p. 1075.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claims are not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 1-6, 9-12, 15-17, 21-24, 25-26, 32-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-12, 15-17, 21-24, 25-26, 29, 30-33 of copending Application 10/676,424 ("App. '424"). A group of claims (29 and 30) is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 of App. '424.

The instant claims recite a method of screening for an effect of a test agent on a population of insects. Claims 29 and 31 limit claims 1, 2, 9, 10, 15, and 24 to a fly and transgenic fly, respectively.

Claims of app. '424 disclose the same method wherein a population of animals is fly larvae. Claim 29 limits claims 1, 2, 9, 10, 15, and 24 to transgenic fly larvae.

Therefore, narrower claims of app. '424 anticipate broader claims of the instant application.

Claim 30 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 of copending Application 10/676,424 ("App. '424"), in view of Botas, US 2004/0177388.

Instant claim 30 is directed to a method of screening for an effect of a test agent on a population of insects wherein insects are *Drosophila* flies.

Claim 29 of app. '424 is directed to the same method wherein an insect is a fly larva.

Claim 29 does not specifically recite *Drosophila*.

Botas discloses a method for identifying agents affecting neurodegenerative disorders using *Drosophila* models wherein the test agents are applied at different stages of *Drosophila* development (*e.g.*, larval stage) ([0292], [0300]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of claim 29 of app. '424 to use *Drosophila* fly models for screening the effect of an agent, such as taught by Botas, where the motivation would have been to facilitate the genetic study of multiple mammalian diseases in a widely used *Drosophila* model, as taught by Botas, [0020], [0106].

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller
Examiner
Art Unit 1631

MM

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
4/6/06